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Patent Application
Attorney's Docket No. 016800-444

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Isabelle NONETTE et al) Group Art Unit: 1617
Application No.: 09/859,384) Examiner: Lauren Q. Wells
Filed: May 18, 2001) Confirmation No.: 3201
For: MANGANESE COMPOSITIONS)
FOR REDUCING/PREVENTING)
SKIN WRINKLES AND FINE LINES)

SECOND
INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In compliance with the requirements of 37 C.F.R. §§ 1.56, 197 and 1.98, applicants are filing herewith a Form PTO-1449 and one copy of each of the documents listed thereon.

The documents listed on the accompanying Form PTO-1449 are in English except for WO 99/62481, FR 2791260 and FR 2612775. Consideration of these French-language documents is requested. The Examiner previously indicated that she did not consider these non-English references when they were initially cited by applicants because no translations were provided. It is respectfully pointed out that applicants are not required to provide translations if none are available to them in order to obtain consideration. However, since a brief statement of relevance is required for non-English documents, and was not submitted earlier, applicants are now resubmitting these non-English documents and providing the following statements of relevance for each of them:

WO 99/62481 includes an English-language abstract. A separate English abstract/patent family search is also appended to the copy of this document. Applicants do not have an English translation of WO 99/62481; however, a copy of its U.S. counterpart, Bonte et al U.S. Patent No. 6,471,972 B1, is also provided herewith. These documents

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**SECOND
INFORMATION DISCLOSURE STATEMENT
TRANSMITTAL LETTER**

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- ☐ No additional fee for submission of an IDS is required.
- ☒ The fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e) is also enclosed.
- ☐ A statement under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (1806) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- ☐ Charge \$_____ to Deposit Account No. 02-4800 for the fee due.
- ☐ A check in the amount of \$_____ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

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Date: February 18, 2003

relate to fighting skin aging effects by using an agent to promote adherence of basal layer keratinocytes to the dermal-epidermal junction. The agent is a divalent metal salt or complex, particularly of magnesium. No specific disclosure of use of a manganese salt for any purpose has been noted. The description and example of the document make reference to the use of magnesium and zinc. Moreover, the salt or metal complex is defined as having a promoting action on the adherence of basal layer keratinocytes to the dermal-epidermal junction; there is no suggestion of any action on the contraction/relaxation mechanism which is the focus of the present invention. The reference thus is not considered detrimental to patentability herein.

FR 2791260 is accompanied by two English-language abstracts and a copy of the cover of the corresponding WIPO publication of the PCT counterpart, WO 00/57836, which also includes an English-language abstract. Applicants do not have an available English translation and have been unable to locate an English-language counterpart. Cosmetic and pharmaceutical compositions are described in which the active agents are α -hydroxy acids or α -keto acids or salts or esters or manganese chloride to increase the expression and/or functionality of CD44 membrane receptors of skin cells, to improve fixation of hyaluronic acid and/or collagen, especially collagen I or collagen IV, and/or fibronectin on the surface of skin cells and improve hydration of the dermis and epidermis and prevent or treat skin-aging phenomena and inflammatory phenomena. There is no mention of any action of manganese on the constriction/relaxation mechanism or of use of manganese for relaxing and/or slackening cutaneous and/or subcutaneous tissue. This is not believed to be detrimental to patentability herein.

FR 2612775 is accompanied by an English-language abstract. Applicants do not have an available English translation and have been unable to locate an English-language counterpart of this document. This reference is directed to the use of ascorbic acid for improving the effect of a combination of vitamin A with "physiologically acceptable compounds" of sulfur, manganese and magnesium on keratinization and sebum production. In all of the examples, the compositions comprise ascorbic acid and a mixture of vegetal

extracts, and sometimes yeast. Bilberry extract is always present in the compositions, which may also comprise soya, artichoke, apricot, spinach and so forth. There is no disclosure of use of a manganese salt per se. There is no mention of any action of manganese on the contraction/relaxation mechanism or use of manganese per se for relaxing and/or slackening cutaneous and/or subcutaneous tissue. The reference is not believed to be relevant to patentability herein.

Also provided herewith is a copy of Murad U.S.P. 5,804,594, which has been cited in applicants' copending Application No. 09/859,392. That copending application has been cited by the Examiner in the September 18, 2002 Official Action herein in an obviousness-type double patenting rejection.

Murad discloses compositions for the prevention and treatment of skin conditions. The skin conditions treated are, according to column 4, lines 32-38 of Murad, those wherein the thickness of the skin needs to be modified. Specific conditions, mentioned in column 4, lines 39-43, are wrinkles, fine lines, thinning, reduced skin elasticity, reduced skin moisture, spider veins, senile purpura, sun damaged skin, aging skin or rough skin. That the conditions contemplated by Murad are related to skin thickness is apparent from much of the disclosure and is abundantly clear from Murad's disclosure of the ingredients of his compositions, for example, in the Summary of the Invention, column 3, lines 26-35: (i) a sugar compound that is converted to a glycosaminoglycan in the patient in an amount sufficient to thicken the skin, (ii) a primary antioxidant component in an amount sufficient to substantially inhibit the activity of collagenase and elastase, (iii) at least one amino acid component in an amount sufficient to assist in the thickening of the skin, and (iv) at least one transition metal component in an amount effective to bind collagen and elastic fibers and rebuild skin. The transition metal component can be zinc, manganese or copper, or mixtures thereof. The specification at its broadest appears to encompass virtually any route of administration, but there is no guidance as to how to use the composition except orally, and Murad's claims are in fact limited to oral compositions and orally administering the compositions; moreover, additional specific ingredients are preferably present. In any

event, Murad uses manganese or other transition metal only in combination with other essential ingredients, not *per se*, and the function of the transition metal is to bind collagen or elastin fibers to strengthen the dermo-epidermal interface. There is no mention or suggestion of any other activity, much less influencing the calcium channels to thus slacken and/or relax cutaneous and/or subcutaneous tissue as in the present invention.

It is requested that the Examiner consider the documents cited by applicants and return an initialed copy of the accompanying Form PTO-1449 to the undersigned with the next official communication.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: March 18, 2003

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